Prevalence Survey of Healthcare-Associated Infections (HAIs) and Antimicrobial Use in U.S. Acute Care Hospitals

Request for Approval of a Nonsubstantive Change

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Contact:
Paulette Ford-Knights
Public Health Analyst
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS D-76
Office: 404-639-4895
Fax: 404-248-4146
E-mail: pbf7@cdc.gov

Prevalence Survey of Healthcare Associated Infections (HAIs) and Antimicrobial Use in U.S. Acute Care Hospitals

This is a request for OMB approval of a nonsubstantive change to an existing data collection, to continue data collections for the Phase 3 Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey, under the OMB control number 0920-0852. This data collection is funded with the American Recovery and Reinvestment Act of 2009 (ARRA) dollars. CDC is requesting a three-year approval to collect the data.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for OMB approval of a data collection for Phase 3 of a three-phase project. The Centers for Disease Control and Prevention (CDC) proposes to conduct surveys to evaluate the prevalence of healthcare-associated infections (HAIs) and antimicrobial use in acute care hospitals in multiple states. This is a three-phase project. The first phase, a small, single-city pilot survey with less than 10 respondents, is complete. Phase 2 was a limited roll-out survey involving 22 healthcare facilities in the 10 states with Emerging Infection Program (EIP) sites; Phase 2 received OMB approval on May 18, 2010. Phase 2 data collection by local infection control personnel in participating hospitals and by EIP personnel is complete and the analysis of Phase 2 data will begin in January 2011. Phase 3 is based upon the operational experience gained in the limited roll-out, and will involve up to 500 facilities in the 10 states with EIP sites (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN) using the same survey. CDC is requesting a minor change to the OMB-approved data collection instrument in Phase 3, described under "Items of Information to be Collected" on page 3. In this data collection, patients are not being interviewed. All information is taken from the medical record.

Healthcare-associated infections (HAIs) and antimicrobial resistance in U.S. acute care hospitals are major public health problems, causing significant morbidity and mortality. Estimating the scope and magnitude of all types of HAIs across all patient populations in U.S. hospitals is essential to the development of effective prevention and control strategies and policies. CDC currently conducts limited HAI surveillance through the National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666, expiration date 09/30/2012), which focuses on incident device- and procedure-associated HAIs in high-risk patient locations; therefore, CDC currently cannot estimate the scope and magnitude of all HAIs affecting the wide spectrum of patient populations in acute care hospitals (i.e., all patient-care locations). Furthermore, CDC does not currently collect detailed data within NHSN or other surveillance systems on antimicrobial use in a national sample of acute care hospitals. Such data are essential in the effort to develop and implement strategies to reduce inappropriate use and prevent the emergence of resistant pathogens. HAI prevalence estimates as well as estimates of antimicrobial use can be obtained through point prevalence surveys, in which data are collected in acute care facilities during a short, specified time period. Although providing only a snapshot of the frequency and nature of HAI and antimicrobial use, point prevalence studies represent a cost-effective alternative to prospective, hospital-wide incidence studies in which the magnitude of HAIs across the wide variety of patient populations can be assessed.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A) and the American Recovery and Reinvestment Act of 2009 (ARRA) (Attachment C).

Privacy Impact Assessment

Overview of the Data Collection System

As in Phase 2, Phase 3 survey data will be collected on paper forms from existing sources of information, including electronic and paper medical records, and entered into a web-based data management system for transmission to CDC. Data collection and data entry partners will include local healthcare facility staff (e.g., Infection Control Practitioners), EIP staff, academic collaborators, and local and state public health professionals. EIP sites will have access to data submitted from facilities within their catchment areas. The information in the CDC database will be maintained indefinitely, since this data collection will be repeated at regular intervals for comparison purposes. Personal identifying information will be maintained by EIP sites until completion of all survey activities, but will not be transmitted to CDC, with the exception of certain dates as described below.

Items of Information to be Collected

Data will be collected through review of existing medical records only. Patients will not be interviewed. Information transmitted to CDC in Phase 3 will include: age, gender, survey date, hospital admission date, state, patient location within the healthcare facility (e.g., medical unit, surgical intensive care unit, etc.), presence of medical devices (urinary catheter, central line, ventilator), antimicrobial treatment (including drug names, route of administration, indication or rationale for use, and therapeutic site), and data on the presence of different types of healthcare-associated infections (including location and dates of onset, causative pathogens, and antimicrobial susceptibility of these pathogens). In Phase 3, local Infection Control Practitioners working conducting the survey in their own hospitals will submit data on patient race and ethnicity that is obtained from the medical record. Although hospital admission date, survey date, and infection and therapy onset dates will be transmitted to CDC, other patient identifiers, such as name, medical record number and address, will not be transmitted to CDC. Each patient will be assigned a unique identification code that will not contain identifying information. CDC will know the names of healthcare facilities that agree to participate in the Phase 3 information collection. For the purposes of data collection and entry, these facilities will be identified by facility identification codes. EIP personnel will be able to link facility identification codes with facility names, but CDC will not have these linkages. Local data collectors in participating healthcare facilities and EIP personnel will need to collect information in identifiable form (IIF) for patients within their own facility or catchment area, such as patient name, date of birth, medical record number, healthcare facility unit name and patient's room number. This information will not be transmitted to CDC.

In Phase 3, data validation will be performed through a Contractor. The Contractor will identify and engage qualified, local or regional expert infection preventionists (referred to as the "Evaluation Team" or "EVALT") to validate data collection in each EIP site. The EVALT will perform retrospective medical record review for a sample of surveyed patients in each EIP site. We anticipate that this sample in each EIP site will consist of an approximately 10-20% random

sample of patients surveyed by local hospital staff and/or EIP personnel. The EVALT will collect similar data as the local hospital staff and EIP personnel (see Attachment B, the OMB-approved data collection form, and the forms included as supplemental information only in Attachment E). However, unlike the Infection Control Practitioners in participating hospitals and EIP personnel, the EVALT will not collect identifiers (i.e., they will not complete the "Identifiers" section shown in Attachment B). The EVALT will also be asked to record on a worksheet the criteria utilized in making HAI determinations for those patients found to have HAIs (see supplemental information, Attachment E).

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The information collection will not involve a website with content directed at children less than 13 years of age.

2. Purpose and Use of Information Collection

Preventing healthcare-associated infections (HAIs) and encouraging appropriate use of antimicrobials are CDC priorities. Essential steps in reducing the occurrence of HAIs and prevalence of resistant pathogens are to estimate accurately the burden of HAIs in U.S. hospitals, describe the types of infections and causative organisms, and assess the nature and extent of antimicrobial use. These goals will be accomplished in the proposed HAI and antimicrobial use prevalence survey.

In 2008-2009, CDC developed and conducted a pilot HAI point prevalence survey (Phase 1). The first phase, a small, single-city pilot survey with less than 10 respondents, is complete. The surveys covered in this application (Phases 2 and 3) expanded the scope of the pilot to include 22 healthcare facilities in 10 states in the Phase 2 limited roll-out survey (OMB-approved on May 18, 2010), followed by the full-scale, Phase 3 survey including up to 500 acute healthcare facilities in the same 10 states.

Facilities participating in Phase 2 were 1-3 volunteer facilities within the catchment areas of each of the 10 EIP sites. In Phase 3, eligible facilities will be those located within the 10 states participating in the EIP (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN). No other states will be included in Phase 3. As required in the Notice of Action (May 18, 2010), we have clarifiedThe proposed facility selection plan in Phase 3 is to draw a random sample of acute care facilities within three bed size strata (small, medium and large facilities) in each EIP site. Each EIP site will aim to engage ≥25 facilities across these three bed size strata, where possible. In some cases, EIP sites will not have enough facilities to meet the 25-facility threshold (for example, a site might only have 24 general acute care hospitals in the entire state). EIP sites will establish the catchment areas they will use for the prevalence survey based on catchment areas used for other EIP surveillance projects. In some cases, EIP sites may consider expansion to additional counties or to the entire state to increase the number of eligible facilities. The decision as to whether an individual EIP site will expand its catchment area is left up to that EIP site.

Facility participation in the Phase 3 survey is voluntary. EIP personnel have established working relationships with infection prevention personnel in healthcare facilities within their catchment areas; we anticipate that these relationships will be strengthened in the coming years as states build their HAI surveillance and prevention activities. For Phase 3, EIP personnel will

recruit facilities to participate through email, telephone and in-person communications. Based on the long-standing relationships that EIP sites have with their facilities, and based on the response from facilities that we experienced in Phases 1 and 2, we do not anticipate that recruitment will present a problem.

Data collected during Phase 3 will be used to estimate HAI prevalence and antimicrobial use in a large sample of U.S. acute care inpatients in the 10 EIP states. As required in the Notice of Action for the Phase 2 survey, we have consulted with colleagues in the National Center for Health Statistics (NCHS, see attached correspondence from Dr. Jane Sisk, Director, Division of Health Care Statistics). Although data collected by the EIP have been used previously to generate national estimates of disease rates (recent examples include invasive pneumococcal disease [29] and methicillin-resistant *Staphylococcus aureus* (MRSA) infections [30]), we will not be able to generate national estimates of HAI prevalence and antimicrobial use from the Phase 3 survey effort. As per Dr. Sisk's consultation letter (see Attachment D), it is not possible at present to utilize administrative data to obtain valid HAI prevalence estimates, nor is it possible to conduct an HAI and antimicrobial use prevalence survey using the existing National Hospital Discharge Survey. Given funding under ARRA and time and resource constraints, we believe that utilizing the EIP infrastructure and facilities in EIP catchment areas to obtain HAI and antimicrobial use prevalence estimates is a reasonable approach and will permit us to gain experience necessary for refining the methodology for future survey efforts that will seek to generate national estimates.

As in Phase 2, EIP personnel and local facility staff members will participate in Phase 3 data collection. Data will be collected on CDC-defined HAIs (using existing NHSN definitions, available at: http://www.cdc.gov/nhsn/PDFs/pscManual/17pscNosInfDef_current.pdf) for a sample of eligible acute care inpatients. In Phase 3 a separate surveillance definition for healthcare-associated *Clostridium difficile* infection will be employed. Patients will be randomly selected from the acute care patient population in each facility on the facility's survey date. Sample size targets will be established for each facility based on factors such as the overall number of participating facilities and the numbers of active acute care beds in each facility. Facilities will supply lists of active bed numbers in advance of the survey date; these lists will be randomly sorted using a random number generator tool. The randomly sorted bed number list will be matched to the facility's patient census list on the morning of the survey. Medical records will be reviewed for each patient on the census list occupying a bed included in the randomly sorted bed number list, up to the target sample size. Patients in outpatient areas of healthcare facilities, including the Emergency Department, will be excluded. Data collected in the Phase 3 survey will be used to estimate the scope and burden of HAIs and antimicrobial use across the EIP sites and to inform efforts to achieve CDC's Health Protection Goals and the prevention of HAIs. This proposed project supports CDC's Strategic Goal of "Healthy Healthcare Settings," specifically the objectives to "Promote compliance with evidence-based guidelines for preventing, identifying, and managing disease in healthcare settings" and "Prevent adverse events in patients and healthcare workers in healthcare settings" (http://www.cdc.gov/osi/goals/places/healthcare.html).

Privacy Impact Assessment

The data collected will be used to determine the prevalence of HAIs, the types of HAIs and causative pathogens, the nature and extent of antimicrobial use in acute care healthcare

facilities, the prevalence of antimicrobial resistance among pathogens causing HAIs, and the prevalence of certain risk factors for infection, such as medical devices. HAIs are recognized as a major cause of morbidity and mortality in the United States, as well as a major contributor to excess healthcare costs (see http://www.hhs.gov/ophs/initiatives/hai/). Eliminating HAIs is a priority of the CDC and other federal agencies. This survey will provide estimates of the magnitude and burden of HAIs in a large sample of U.S. acute care inpatients forming the foundation for development and implementation of effective prevention measures. During this data collection, CDC will neither receive nor share IIF, with the exception of medical information as described above. With the exception of race and ethnicity, no sensitive information is being collected on individual patients. Data will be entered into the electronic data management system and retrieved by CDC using identification codes that do not contain patient identifiers. CDC will analyze and report aggregated data obtained during the survey. The results of the survey will be used by local, state and federal public health authorities to inform the development of HAI prevention strategies and policies. Individual healthcare facilities may also use the data to inform institution-level practice and policy.

3. Use of Improved Information Technology and Burden Reduction

As in Phase 2, the Phase 3 survey will use paper data collection forms because survey personnel will need to travel to multiple patient units within healthcare facilities to collect data and will not necessarily have reliable, timely access to computers or the internet. All data will be entered by survey personnel into a web-based, electronic data management system. No paper forms with personal identifiers such as name or medical record number will be submitted to CDC. Dates as noted above will be recorded on paper forms and in the electronic data management system, and will be submitted to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

CDC's first HAI prevalence survey was conducted in the 1970s (Study on the Efficacy of Nosocomial Infection Control, SENIC), using a team of trained abstractors to collect comprehensive HAI data from a probability sample of 338 hospitals [2]. The SENIC project found that approximately 5% of hospitalized patients acquired an infection not present or incubating at the time of admission [3]. At a cost of $27 million, the SENIC project has not been repeated. In the 1980s and 1990s CDC conducted voluntary, hospital-wide infection surveillance through the National Nosocomial Infections Surveillance (NNIS) system (OMB Control Number 0920-0012); in NNIS, data were reported from local hospital personnel rather than a common team of CDC-trained data collectors (http://www.cdc.gov/ncidod/dhqp/nnis.html). As demands on infection control grew, voluntary NNIS hospitals began to perform targeted surveillance in high-risk hospital areas (such as intensive care units) that were most useful in calculating risk-adjusted HAI incidence rates. The NNIS system's hospital-wide HAI surveillance component was eliminated in 1996. CDC's successor to the NNIS system, the National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666), is not designed to estimate the scope and magnitude of HAIs hospital-wide; rather, it focuses on device-associated and procedure-associated infections (central-line associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections, ventilator-associated pneumonia and post-procedure pneumonia) (http://www.cdc.gov/nhsn/about.html). In its current form, the NHSN cannot provide estimates of HAI for all types of HAIs or antimicrobial use throughout an entire hospital. Measurements of the magnitude and types of HAIs and nature and extent of antimicrobial use

occurring across all acute care patient populations are needed to inform decisions by local and national policy makers and by hospital infection control personnel regarding appropriate targets and strategies for HAI prevention, measures to encourage appropriate antimicrobial use, and/or justification to focus efforts at specific antimicrobial resistant infections. Such measurements, while not possible within the current NHSN infrastructure, can be obtained in prevalence surveys. Such surveys have been conducted in several countries around the world in recent years [4-28]; no such recent, national-scale effort has occurred in the United States. There are no duplicate efforts underway within the United States.

While the information collected in the prevalence survey is broader in scope than the data collected in the NHSN, there may be some minimal overlap. It is important to note that while we estimate that approximately 3% of the HAIs identified in the prevalence survey in a given hospital will have to be entered in to the NHSN system, each facility will conduct the prevalence survey over a very short period of time (one day) and will only be collecting data on a sample of patients in the facility during that short time period. For example, a hospital with 500 acute care beds may be asked to review 100 patients' medical records for the purposes of the prevalence survey. If 7% of these patients have HAIs (7 patients) and we estimate that 3% of HAIs detected will also need to be entered into NHSN, that represents a burden of less than one patient record for that facility.

5. Impact on Small Businesses or Other Small Entities

Small hospitals may participate in Phase 3 of the prevalence survey. Participation is voluntary, but we anticipate that most facilities selected for participation will agree to participate. Elimination of HAIs is a major goal of all U.S. healthcare institutions, large and small, and we expect that facilities will be highly motivated to participate. This has been our experience in developing the single-city pilot effort as well as the Phase 2 effort. The data collection and management burden for participating healthcare facilities will be minimized as much as possible. This will be accomplished by having EIP personnel perform most of the data collection.

6. Consequences of Collecting the Information Less Frequently

As Phase 2 survey activities near completion, facilities will be asked to participate in the Phase 3 prevalence survey, with the possibility that the survey will be repeated at regular but infrequent intervals in the future (once every 3-5 years). Repeating the survey will provide information on changes in HAI prevalence over time as well as changes in the burden and distribution of infection types and causative organisms. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances that require the information to be collected in any of the formats identified, and the request fully complies with regulations.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

No Federal Register applicable.

9. Explanation of Any Payment or Gift to Respondents

Participating healthcare facilities may receive a certificate or letter of appreciation.

10. Assurance of Confidentiality Provided to Respondents

As in Phase 2, a unique identifier will be assigned to each patient included in Phase 3 to allow the reporting facility and EIP site to link reported data back to the individual patient, however this link will not be shared with CDC. Hospital admission date and other dates as noted above will be transmitted to CDC; patient identifiers such as date of birth, medical record number and name will not be transmitted to CDC. Each facility will also have an assigned identification code. Although CDC will know the identities of participating healthcare facilities, data collection forms will be filled out using patient and facility codes. Links between facility codes and names will be maintained by EIPs and will not be shared with CDC. Individual facility data will not be reported by CDC (although individual facilities may have access to their own data), but rather will be aggregated to provide HAI and antimicrobial use prevalence estimates. All patient-level data will be kept in a secure manner and will not be disclosed unless otherwise compelled by law. The data management system for Phase 2 was certified and accredited as a Level 1 system. The same data management system will be used for Phase 3, with some minor modifications. These modifications will also undergo the appropriate approval processes prior to implementation.

Privacy Impact Assessment

A) This information collection request has been reviewed by CDC/ICRO who has determined that the Privacy Act does not apply. Patients included in the survey will be assigned unique identification codes; these codes will not contain identifying information. With the exception of certain dates, personal identifiers will not be transmitted to CDC.

B) Information received by CDC will be stored in a secure, password-protected database. Information received by CDC will be provided only to those individuals at CDC with a need to know.

C) Respondent consent: Not applicable. Individual persons are not the survey respondents in this case. Data collectors, including EIP personnel, will perform review of existing medical record data in participating facilities and submit these data to CDC. There is no interaction with individual patients.

D) Participation by facilities in this project is voluntary. Data will be treated in a secure manner, and will not be disclosed, unless otherwise compelled by law.

11. Justification for Sensitive Questions

Information on criminal behavior, sexual behavior and attitudes, alcohol or drug use, and religious beliefs, will not be collected. Race and ethnicity will be collected by local hospital staff and EIP personnel in the Phase 3 survey. In this data collection, patients are not being interviewed. All information is taken from the medical record. We believe it is important to collect data on race and ethnicity in the Phase 3 survey because studies have indicated that there is a higher burden of some types of healthcare-associated infections in minority patients. For example, a study published in 2010 showed that post-operative infections were significantly more common among black patients than white patients [31]. Similarly, data from the Emerging Infections Program's invasive MRSA surveillance have shown that the incidence of healthcare-associated invasive MRSA infections was significantly higher in black persons than in white

persons [30]. The reporting of adverse events occurring in hospitalized patients, including infections, could be considered sensitive unless healthcare facilities are assured that the data-aggregating organization will provide security for the data. Data security will be assured as described above.

12. Estimates of Annualized Burden Hours and Costs

A. Infection Control Practitioners in participating healthcare facilities in Phase 3 will be asked to collect a minimal amount of data, limited to basic demographic and risk factor/antimicrobial use information. We anticipate that this data collection will take 7 minutes per patient. Based on our Phase 2 experience and the anticipated large variability in facility record systems in Phase 3, we have added additional time per patient in Phase 3 for training and other survey-related activities.

In estimating the burden on Infection Control Practitioners in healthcare facilities participating in the Phase 3 survey, we have incorporated knowledge gained from the conduct of the Phase 2 survey. Based on our Phase 2 experience, an alternative patient sampling method will be utilized in Phase 3 to encourage facility engagement and improve work flow. EIP sites will ask each participating facility to survey a fixed number of patient records, 75-100 randomly-selected acute care inpatients, depending upon hospital size. We expect that small and medium facilities will be asked to survey 75 patients each (or, if the hospital has <75 beds, the facility will survey all patients), while large hospitals will be asked to survey 100 patients each. Small hospitals are anticipated to account for approximately 60% of facilities in the survey (and not all of these hospitals will have 75 patients to survey), medium hospitals are estimated to account for approximately 30% of facilities in the survey, and large hospitals are estimated to account for approximately 10% of facilities in the survey. With an estimated 500 facilities participating in the survey, 300 of these will be small hospitals, 150 will be medium hospitals, and 50 will be large hospitals. Of the 300 small hospitals, we estimate that 70% of these are large enough that they are able to review 75 patients, while in the other 30%, we estimate that 50 patients will be available for review. Therefore, the total number of records reviewed is as follows: [(210 small facilities)*(75 records)] + [(90 small facilities)*(50 records)] + [(150 medium facilities)*(75 records)] + [50 large facilities)*(100 records)] = 36,500 records, which translates to an average of 73 responses per respondent.

As noted above, we have estimated 7 minutes for data collection form completion per patient. To allow for circumstances in which total time to survey each patient is longer (such as facilities with paper medical records where data collectors must travel between units), we have added an additional 5 minutes per response, and to account for additional training and other survey activities for each respondent, we have added an additional 3 minutes per response. Therefore, in Table A below, Row #1 includes the time for training and other survey activities averaged out on a per response basis (3 minutes), and Row #2 includes time for completing the data collection form and additional time for traveling in the hospital, accessing the medical record, etc. (7 minutes + 5 minutes = 12 minutes). The total average estimated time per response is the sum of Rows #1 and 2, or 15 minutes.

The total burden <u>per respondent</u> is therefore estimated to equal (13 minutes per response)*(73 responses), or 16 hours.

During a May 7, 2010 teleconference with Dr. Margo Schwab and Ms. Julie Wise from OMB, Dr. Schwab informed CDC prevalence survey personnel that because the Emerging Infections Program is a CDC-run program under a Cooperative Agreement, EIP personnel should not be included in the annualized burden estimate. EIP personnel in Phase 3 will perform comprehensive medical record review to collect detailed information on antimicrobial use and HAIs. The data collection forms that will be completed by EIP personnel are included in Attachment E as supplemental information. In some cases, EIP personnel may also assist Infection Control Practitioners in participating hospitals with the completion of the data collection form shown in Attachment B. EIP personnel time is not included in the burden estimate.

Similarly, because the Contractor performing the validation component of the survey is being paid to collect data on behalf of the government, Contractor time is not included in the burden estimate.

Table A: Estimated Annualized Burden Hours for Phase 3

Type of Respondent	***Form Name***	***Number of Respondents***	***Number of Responses per Respondent***	***Average Burden per Responses (in hours)***	***Total Burden Hours***
Infection Control Practitioners	**No form: Training and other activities	500	73	3/60	1,825
Infection Control Practitioners	Primary Team / EIP Team Data Collection Form	500	73	12/60	7,300
Total					9,125

B. The total cost burden for the Infection Control Practitioner respondents in healthcare facilities participating in Phase 3 is estimated as follows: With a total annual burden of 9,125 hours for Phase 3, the total cost of the time to respond to the proposed survey is estimated to be $291,908.75 ([9,125 hours]*[$31.99], Table B). We have utilized the mean hourly wage for a Registered Nurse, $31.99, obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2009 data (accessed January 27, 2011 at http://www.bls.gov/oes/current/oes291111.htm). We utilized this wage because: 1) Infection Control Practitioners are in many cases Registered Nurses; and 2) there is no wage information specifically for Infection Control Practitioners available in the Bureau of Labor Statistics database cited above. There will be no direct costs to facilities and local data collectors other than their time to participate in the study.

Table B: Phase 3 Estimated Annualized Burden Costs for Phase 3

Respondent	***Total Burden Hours***	***Hourly Wage Rate***	***Total Respondent***

			Cost
Registered Nurse (surrogate for Infection Control Practitioner)	9,125	$31.99	$291,908.75

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

None.

14. Annualized Cost to the Government

For Phase 3, costs to the government include costs for CDC epidemiologists to develop and coordinate survey activities, EIP personnel to perform local survey coordination and data collection and entry activities, costs for a database manager, costs for photocopying survey materials, and costs for an external Contractor to perform data validation activities.

CDC personnel working on the Phase 3 survey are estimated to include a 0.3 full-time-equivalent (FTE) epidemiologist (see Row #1 of Table C) and a 0.2 FTE database manager (see Row #2 of Table C). The mean hourly wage for an epidemiologist is $31.22 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2009 data, available at: http://www.bls.gov/oes/current/oes191041.htm), for a total cost of $19,481. The mean hourly wage for a database administrator is $35.72 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2009 data, available at: http://www.bls.gov/oes/current/oes191041.htm), for a total cost of $14,859.

EIP sites (see Row #3 of Table C) are supported through a Cooperative Agreement with CDC. We estimate that on an annualized basis, 1.5 FTE employees are needed in each site to conduct Phase 3 survey activities. These employees are epidemiologists, with an estimated hourly wage of $31.22 and annual wage of $64,950 (obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2009 data, available at: http://www.bls.gov/oes/current/oes191041.htm). Therefore, in each EIP site, the estimated annual cost is $97,425.00. The estimated cost across the 10 EIP sites is $974,250.00.

CDC will work with a Contractor (see Rows #4 and #5 of Table C) to identify external expert infection preventionists to perform data validation in Phase 3. These expert infection preventionists will comprise the Evaluation Team, or EVALT. We estimate that the EVALT will review approximately 5,475 medical records. Review time for each record is estimated to be 15 minutes; an additional 15 minutes per record has been added to account for additional training and other survey-related activities. Based on previous experience, the hourly cost for these medical record reviews is estimated to be $100.00. The total cost for record review alone is therefore estimated to be $273,750. We estimate an additional $100,000 for coordination and travel- and supply-related expenses. The total estimated cost of this contract is therefore $373,750.

Table C: Annualized cost to the federal government for Phase 3

Government Employee Title	***Total Number of Hours Dedicated to***	***Hourly Rate***	***Total Burden per Year***

	Survey per Year		
CDC surveillance epidemiologist	624	$31.22	$19,481
Database manager	416	$35.72	$14,859
EIP epidemiologists (1.5 FTE in each of 10 sites)	31,206	$31.22	$974,250
Contractor—Phase 3 Data Validation	2,738	$100	$273,750
Contractor—Phase 3 Data Validation travel, coordination and supply–related costs	--	--	$100,000
Total personnel cost			$1,382,340

There will also be costs related to photocopying of survey forms and instructions. In Phase 3, the cost is estimated to be $8,000 ($0.05 to copy each page, estimated 160,000 copies made to support survey activities in 500 facilities in 10 EIP sites).

The total annualized cost to the federal government for personnel and photocopying in Phase 3 is therefore estimated to be $1,382,340 + $8,000 = $1,390,340.

15. Explanation for Program Changes or Adjustments

This request for approval of a nonsubstantive change is being submitted in accordance with the instructions provided by OMB in its Notice of Action for the Information Collection Request (ICR) identified by the Control Number 0920-0852. This ICR was approved on May 18, 2010. The ICR consisted of two data collection phases, referred to as Phase 2 and Phase 3. OMB approved the Phase 2 data collection, but stipulated the need to submit a change request satisfying two Terms of Clearance before the Phase 3 data collection could commence.

The Notice of Action specifically states the following: “CDC must submit a change package for Phase 3. The package for Phase 3 must define the scope (i.e., whether facilities outside of usual EIP catchment areas will be included) as well as the results of discussions with NCHS about using the 10 EIPs areas to characterize a national estimate.”

We have satisfied the Terms of Clearance, as outlined in this revised Supporting Statement. We are now submitting the required “Request for Approval of a Nonsubstantive Change” so that we may proceed with Phase 3, a project funded by the American Recovery and Reinvestment Act (ARRA).

Changes to burden hours for Phase 3 were made based upon our experience in the Phase 2 survey, and on the anticipated changes in the number and characteristics of hospitals participating in the Phase 3 survey and on anticipated training and data collection needs for Phase 3 survey personnel.

16. Plans for Tabulation and Publication and Project Time Schedule

A patient-level surveillance dataset is maintained at CDC. This dataset will be used to determine HAI prevalence (e.g., number of HAIs or number of patients with HAIs / total number of patients surveyed), antimicrobial use prevalence (e.g., number of patients on antimicrobials / total number of patients surveyed), the distribution of HAI types and causative organisms, and the distribution of types of antimicrobials and rationale for their use. Analysis will occur in SAS version 9.2 (SAS Institute, Carey, NC).

Publication

Results from this survey will be presented at national meetings and published in a manuscript format in a peer-reviewed scientific journal. Publications will include a discussion of potential biases and other limitations of the project.

Project time schedule

Phase 3 will be conducted as soon as possible following OMB approval. Because of funding concerns and the need to complete the Phase 3 survey during the period covered by the American Recovery and Reinvestment Act of 2009, our goal is to conduct the Phase 3 survey as soon as possible in 2011, ideally in May and June 2011 (see Table D below).

Table D: Project time schedule

Activity	*Time Schedule*
Training of Infection Control Practitioners in participating hospitals	Immediately, or within 1-2 months after OMB approval (April 2011)
Conduct of Phase 3 survey	Within 2-4 months after OMB approval (May-July 2011)
Data collection by EIP personnel	Within 3-7 months after OMB approval (June-November 2011)
Transmission of Phase 3 data to CDC	Within 8 months after OMB approval (December 2011)
Analysis and presentation of Phase 3 results	Within 8-12 months after OMB approval (December 2011-March 2012)
Repeat of survey	Approximately 24 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The proposed survey instrument (Attachment B) will display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This data collection has been designed in accordance with the requirements specified in Item 19 of the OMB 83-I. No exceptions to certification are requested.

References

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List of Attachments

A: United States Code, Title 42, Chapter 6A Part 241

B: Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey Data Collection Form

C: American Recovery and Reinvestment Act of 2009

D. Email correspondence from Dr. Jane Sisk, Director, Division of Healthcare Statistics, National Center for Health Statistics

E. Supplemental information: data collection forms utilized by EIP personnel and the Contractor, but NOT completed by Infection Control Practitioners in participating healthcare facilities